AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

106TH CONGRESS
2D SESSION

S. 3184

To amend the Federal Food, Drug, and Cosmetic Act to require premarket consultation and approval with respect to genetically engineered foods, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 11 (legislative day, SEPTEMBER 22), 2000

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require premarket consultation and approval with respect to genetically engineered foods, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genetically Engineered Foods Act''.

SEC. 2. FINDINGS.

Congress finds that—

(1) genetically engineered food is rapidly becoming an integral part of the United States and international food supplies;

(2) the potential positive effects of genetically engineered foods are enormous;

(3) the potential for negative effects, both anticipated and unexpected, exists with genetic engineering of foods;

(4) evidence suggests that unapproved genetically engineered foods are entering the food supply;

(5) it is essential to maintain public confidence in the safety of the food supplies and in the ability of the Federal government to exercise adequate oversight of genetically engineered foods;

(6) public confidence can best be maintained through careful review of new genetically engineered foods, and monitoring of the positive and negative effects of genetically engineered foods as the foods become integrated into the food supplies, through a review and monitoring process that is scientifically sound, open, and transparent, and that fully involves the general public; and

(7) since genetically engineered foods are developed worldwide and imported into the United States, it is also imperative to ensure that imported geneti-

cally engineered foods are subject to the same level of oversight as domestic genetically engineered foods.

SEC. 3. PREMARKET REVIEW OF GENETICALLY ENGINEERED FOODS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 414. GENETICALLY ENGINEERED FOODS.

''(a) DEFINITIONS.—In this section:

''(1) GENETIC ENGINEERING.—The term 'genetic engineering' means the application of a recombinant DNA technique or a related technology to modify genetic material with a degree of specificity or precision that is not usually available with a conventional breeding technique or another form of genetic modification.

''(2) GENETICALLY ENGINEERED FOOD.—The term 'genetically engineered food' means a food or dietary supplement that—

''(A)(i) is produced in a State; or

''(ii) is offered for import into the United States; and

''(B) is created by genetic engineering.

''(3) PRODUCER.—The term 'producer', used with respect to a genetically engineered food means a person, company, or other entity that develops, manufactures, imports, or takes other action to introduce into interstate commerce, a genetically engineered food.

''(4) SAFE.—The term 'safe', used with respect to a genetically engineered food, means that the food is considered to be as safe as the appropriate comparable food that is not created by genetic engineering.

''(b) REGULATIONS FOR GENETICALLY ENGINEERED FOODS.—

''(1) PREMARKET CONSULTATION AND APPROVAL.—

''(A) IN GENERAL.—The Secretary shall issue regulations that require a producer of a genetically engineered food, in order to obtain the approval described in subparagraph (B), to use a premarket consultation and approval process described in subparagraph (C).

''(B) APPROVAL.—The regulations shall require the producer to use the process in order to obtain approval to introduce the food into interstate commerce, except in cases where the

producer has previously successfully completed the process described in subparagraph (C) or the voluntary premarket consultation process described in paragraph (2).

''(C) PROCESS.—The regulations shall require the producer to use a premarket consultation and approval process that—

''(i) includes the procedures of the voluntary premarket consultation process described in paragraph (2); and

''(ii) meets the requirements of this subsection.

''(2) VOLUNTARY PREMARKET CONSULTATION PROCESS.—The process referred to in paragraph (1)(C)(i) is the voluntary premarket consultation process described in—

''(A) the guidance document entitled 'Guidance on Consultation Procedures: Foods Derived From New Plant Varieties', issued in October 1997, by the Office of Premarket Approval of the Center for Food Safety and Applied Nutrition, and the Office of Surveillance and Compliance of the Center for Veterinary Medicine, of the Food and Drug Administration

(or any corresponding similar guidance document);

''(B) the statement of policy entitled 'Foods Derived From New Plant Varieties', published in the Federal Register on May 29, 1992, 57 Fed. Reg. 22984 (or any corresponding similar statement of policy); and

''(C) such other documents issued by the Commissioner relating to such process as the Secretary may determine to be appropriate.

''(3) SUBMISSION AND DISSEMINATION OF MATERIALS.—

''(A) SUBMISSION.—The regulations shall require that, as part of the consultation and approval process, each producer of a genetically engineered food submit to the Secretary—

''(i) each summary of research, test results, and other materials that the producer is required to submit under the process described in paragraph (2); and

''(ii) a copy of the research, test results, and other materials.

''(B) DISSEMINATION.—On receipt of a request for the initiation of a consultation and approval process, or on receipt of such sum-

mary, research, results, or other materials for a food, the Secretary shall provide public notice regarding the initiation of the process, including making the notice available on the Internet. The Secretary shall make the summaries, research, results, and other materials relating to the food publicly available, including, to the extent practicable, available on the Internet, prior to making any determination under paragraph (4).

''(C) PROTECTION OF TRADE SECRETS.—The regulations shall ensure that laws in effect on the date of enactment of the Genetically Engineered Foods Act that protect trade secrets apply with respect to the information submitted to the Secretary under subparagraph (A). Such regulations may provide for the submission of sanitized information in appropriate cases, and the dissemination of such sanitized information.

''(4) DETERMINATIONS.—The regulations shall require that, as part of the consultation and approval process for a genetically engineered food, the Secretary shall—

''(A) determine whether the producer of the food has submitted, during the consultation,

materials and information that are adequate to enable the Secretary to fully assess the safety of the food, and make a description of the determination publicly available; and

''(B) if the Secretary determines that the producer has submitted adequate materials and information, conduct a review of the materials and information, and, in conducting the review—

''(i) prepare a response that—

''(I) summarizes the materials and information;

''(II) explains the determination; and

''(III) contains a finding by the Secretary that the genetically engineered food—

''(aa) is considered to be safe and may be introduced into interstate commerce;

''(bb) is considered to be conditionally safe and may be so introduced if certain stated conditions are met; or

"(cc) is not considered to be safe and may not be so introduced;

"(ii) make the response publicly available; and

"(iii) provide an opportunity for the submission of additional views or data by interested persons on the response.

"(5) REVIEW FOR CAUSE.—

"(A) REQUEST FOR ADDITIONAL REVIEW.—The regulations shall provide that any person may request that the Secretary conduct an additional review, of the type described in paragraph (4)(B), for a food on the basis of materials and information that were not available during an earlier review described in paragraph (4)(B) or that were not considered during the review.

"(B) FINDING FOR ADDITIONAL REVIEW.—The Secretary shall conduct the additional review, on the basis of the materials and information described in subparagraph (A) if the Secretary finds that the materials and information—

"(i) are scientifically credible;

"(ii) represent significant materials and information that was not available or considered during the earlier review; and

"(iii) suggest potential negative impacts relating to the food that were not considered in the earlier review or demonstrate that the materials and information considered during the earlier review were inadequate for the Secretary to make a safety finding.

"(C) ADDITIONAL MATERIALS AND INFORMATION.—In conducting the additional review, the Secretary may require the producer of the genetically engineered food to provide additional materials and information, as needed to facilitate the review.

"(D) FINDING.—In conducting the review, the Secretary shall—

"(i) issue a response described in paragraph (4)(B) that revises the finding made in the earlier review with respect to the safety of the food; or

"(ii) make a determination, and issue an explanation stating, that no revision to the finding is needed.

''(E) ACTION OF SECRETARY.—If, based on a review under this paragraph, the Secretary determines that the food involved is not safe, the Secretary may withdraw the approval of the food for introduction into interstate commerce or take other action under this Act as the Secretary determines to be appropriate.

''(6) EXEMPTIONS.—

''(A) CATEGORIES OF GENETICALLY ENGINEERED FOODS.—

''(i) PROPOSED RULE.—The Secretary may issue a proposed rule that exempts a category of genetically engineered foods from the regulations described in paragraph (1) if—

''(I) the rule contains a narrowly specified definition of the category;

''(II) the rule specifies the particular foods included in the category;

''(III) the rule specifies the particular genes, proteins, and adjunct technologies (such as use of markers or promoters) that are involved in the genetic engineering for the foods included in the category; and

''(IV) not less than 10 foods in the category have been reviewed under paragraph (4)(B) and found to be safe.

''(ii) PUBLIC COMMENT PERIOD.—The Secretary shall provide an opportunity, for not less than 90 days, for the submission of comments by interested persons on the proposed rule.

''(iii) FINAL RULE.—At the end of the comment period described in clause (ii), the Secretary shall issue a final rule described in clause (i).

''(B) REGULATED GENETICALLY ENGINEERED FOODS.—

''(i) PROPOSED RULE.—The Secretary may issue a proposed rule that exempts from the regulations described in paragraph (1) genetically engineered foods that the Secretary determines are subject to regulation under Federal law other than this section, such as foods from pharmaceutical-producing plants.

''(ii) PUBLIC COMMENT PERIOD.—The Secretary shall provide an opportunity, for

not less than 90 days, for the submission of comments by interested persons on the proposed rule.

''(iii) FINAL RULE.—At the end of the comment period described in clause (ii), the Secretary shall issue a final rule described in clause (i).

''(7) ISSUANCE DATES.—The Secretary shall issue proposed regulations described in paragraph (1) not later than 6 months after the date of enactment of the Genetically Engineered Foods Act, and final regulations described in paragraph (1) not later than 18 months after such date of enactment.

''SEC. 415. REPORTS ON GENETICALLY ENGINEERED FOODS.

''(a) DEFINITIONS.—In this section, the terms 'genetic engineering' and 'genetically engineered food' have the meanings given the terms in section 414.

''(b) GENERAL AUTHORITY.—The Secretary, the Administrator, and the Secretary of Agriculture (referred to in this section as the 'covered officers'), after consultation with the Secretary of Commerce, the Secretary of the Interior, the Council on Environmental Quality, and the heads of such other agencies as the covered officers may determine to be appropriate, shall jointly prepare and submit

to the appropriate committees of Congress reports on genetically engineered foods and related concerns.

''(c) CONTENTS.—The reports shall contain—

''(1) information on the types and quantities of genetically engineered foods being offered for sale or being developed, domestically and internationally;

''(2) information on current and emerging issues of concern relating to genetic engineering, including issues relating to—

''(A) the ecological impacts of, antibiotic markers for, insect resistance to, nongerminating or terminator seeds for, or cross-species gene transfer for, genetically engineered foods;

''(B) foods from animals created by genetic engineering;

''(C) non-food crops, such as cotton, created by genetic engineering; and

''(D) socioeconomic concerns (such as the impact of genetically engineered foods on small farms), and liability issues;

''(3) information on options for labeling genetically engineered foods, the benefits and drawbacks of each option, and an assessment of the authorities under which such labeling might be required;

''(4) a response to and information on the status of implementation of the recommendations contained in a report entitled 'Genetically Modified Pest Protected Plants', issued in April 2000, by the National Academy of Sciences;

''(5) an assessment of data needs relating to genetically engineered foods;

''(6) a projection of the number of genetically engineered foods that will require regulatory review in the next 5 years, and the adequacy of the resources of the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture to conduct the review; and

''(7) an evaluation of the national capacity to test foods for the presence of genetically engineered ingredients.

''(d) SUBMISSION OF REPORTS.—The covered officers shall submit reports described in this section not later than 2 years, 4 years, and 6 years after the date of enactment of the Genetically Engineered Foods Act.

''SEC. 416. MARKETPLACE TESTING.

''(a) IN GENERAL.—The Secretary, in conjunction with the Secretary of Agriculture and the Administer of the Environmental Protection Agency, shall establish a program to conduct testing, as determined necessary by

the Secretary, to identify genetically engineered foods at all stages of production (from the farm to the retail store).

''(b) PERMISSIBLE TESTING.—Under the program under subsection (a), the Secretary may conduct tests on foods —

''(1) to identify genetically engineered ingredients that have not been approved for use pursuant to this Act, including foods that are developed in foreign countries that have not been approved for marketing in the United States under this Act; and

''(2) to identify the presence of genetically engineered ingredients the use of which is restricted under this Act (including approval for animal feed only, approval only if properly labeled, approval for growing or marketing only in selected regions).

''SEC. 417. GENETICALLY ENGINEERED FOOD REGISTRY.

''(a) ESTABLISHMENT.—The Secretary, in conjunction with the Secretary of Agriculture and the Administer of the Environmental Protection Agency, shall establish a registry for genetically engineered foods that contains a description of the regulatory status of all such foods that have been submitted to the Secretary for premarket approval and that meets the requirements of subsection (b).

''(b) REQUIREMENT.—The registry established under subsection (a) shall—

''(1) identify all genetically engineered food that have been submitted to the Secretary for premarket approval;

''(2) contain the technical and common names of each of the foods identified under paragraph (1)

''(3) contain a description of the regulatory status under this Act of each of the foods identified under paragraph (1);

''(4) contain a technical and non-technical summary of the types of genetic changes made to each of the foods identified under paragraph (1) and the reasons for such changes;

''(5) identify an appropriate public contact official at each entity that has created each of the foods identified in paragraph (1);

''(6) identify an appropriate public contact official at each Federal agency with oversight responsibility over each of the foods identified in paragraph (1); and

''(7) be accessible by the public.''.

SEC. 4. PROHIBITED ACTS.

Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(h) If it is a food containing a genetically engineered food as an ingredient, or is a genetically engineered food (as defined in section 414(a)) that is subject to section 414(b) that—

''(1) does not meet the requirements of section 414(b); and

''(2)(A) is produced in the United States and introduced into interstate commerce by a producer (as defined in section 414(a)); or

''(B) is introduced into interstate commerce by an importer.''.

SEC. 5. GRANTS FOR RESEARCH ON ECONOMIC AND ENVIRONMENTAL RISKS AND BENEFITS OF USING BIOTECHNOLOGY IN FOOD PRODUCTION.

(a) IN GENERAL.—Section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) is amended by striking subsections (a) and (b) and inserting the following:

''(a) PURPOSES.—The purposes of this section are—

''(1) to authorize and support research intended to identify and analyze technological developments in the area of biotechnology for the purpose of evaluating the potential positive and adverse effects of the developments on the United States farm economy and the environment, and addressing public concerns

about potential adverse environmental effects, of using biotechnology in food production; and

''(2) to authorize research to help regulatory agencies develop policies, as soon as practicable, concerning the introduction and use of biotechnology.

''(b) GRANT PROGRAM.—The Secretary of Agriculture, acting through the Cooperative State Research, Education, and Extension Service and the Agricultural Research Service, shall establish a competitive grant program to conduct research to promote the purposes described in subsection (a).''.

(b) TYPES OF RESEARCH.—Section 1668(c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921(c)) is amended—

(1) by redesignating paragraph (4) as paragraph (5); and

(2) by inserting after paragraph (3) the following:

''(4) Research designed to evaluate—

''(A) the potential effect of biotechnology developments on the United States farm economy;

''(B) the competitive status of United States agricultural commodities and foods in foreign markets; and

''(C) consumer confidence in the healthfulness and safety of agricultural commodities and foods.''.

(c) PRIORITY.—Section 1668(d)(1) of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921(d)(1)) is amended by inserting before the semicolon the following: '', but giving priority to projects designed to develop improved methods for identifying potential allergens in pest-protected plants, with particular emphasis on the development of tests with human immune-system endpoints and of more reliable animal models''.

(d) CONFORMING AMENDMENTS.—

(1) Section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) is amended by striking the section heading and inserting the following:

''SEC. 1668. GRANTS FOR RESEARCH ON ECONOMIC AND ENVIRONMENTAL RISKS AND BENEFITS OF USING BIOTECHNOLOGY IN FOOD PRODUCTION.''.

(2) Section 1668(g)(2) of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921(g)(2)) is amended by striking ''for research on biotechnology risk assessment''.

○